



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

National Institute of Mental Health Recruitment and Milestone Reporting System (NIMH)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Mental Health (NIMH), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection

techniques or other forms of information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Keisha Shropshire, NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Rockville Pike, Bethesda, MD 20892, or call 301-443-4335 or E-mail your request, including your address to: nimhprapubliccomments@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments received within 60 days of the date of this publication will receive fullest consideration.

PROPOSED COLLECTION: The National Institute of Mental Health Recruitment Milestone Reporting System (NIMH); REVISION; OMB Control Number 0925-0697. National Institute of Mental Health, National Institutes of Health.

Need and Use of Information Collection: Recruitment Milestone Reporting (RMR) allows NIMH staff to monitor more accurately the required recruitment of participants in NIMH-sponsored clinical trials and other clinical research studies that plan to enroll 150 or more human subjects in a single study. Clinical studies can have difficulty recruiting, and accurate and timely reporting is the best way to ensure proper use of the grant funds. Investigators develop a recruitment plan that includes tri-yearly milestones for recruitment of the total study population, and for recruitment of racial and

ethnic minority participants. Once recruitment is scheduled to begin, investigators report actual progress on recruitment milestones three times per year, by April 1, August 1, and December 1. Studies that fail to meet their milestones may be requested to provide interim monthly reports. The primary use of this information is to ensure that realistic recruitment targets are established from the onset of a project, and that these targets are met throughout the course of the research. By ensuring timely recruitment into clinical research studies, NIMH can reduce the need to extend timelines or supplement funds in order to complete the research project, and potentially increase efficiency in our funding process.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2295.

Estimated Annualized Burden Hours

Form	Type of Respondent	Number of Respondents	Frequency of Response	Average time per response (in hours)	Annual hour burden
NIMH Recruitment Milestone Reporting	Principal Investigators/ Research Assistant	900	3	45/60	2025
NIMH Recruitment Milestone Monthly Report	Principal Investigators/ Research Assistant	40	9	45/60	270

Dated: May 21, 2015.

Keisha L Shropshire

Project Clearance Liaison

NIMH, NIH

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